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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,235	11/06/2001	Seth Lederman	2516-1-002N	5392

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER	
DELACROIX MUIRHEI, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/992,235	LEDERMAN ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-22 are presented for prosecution on the merits.

Claim Objections

1. Claim 17 is objected to because of the following informalities: method claim 17 is dependent upon claim 5, a composition claim. Method claims cannot depend from composition claims. Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al., 5,462,746 or Midha et al., 6,217,904.

Wolter et al. disclose a patch for transdermal administration of pharmaceutically active agents such as amphetaminil. Wolter et al. further disclose that said patches are useful in methods for treating patients suffering from Parkinson's disease or Alzheimer's disease. Please refer to the abstract; col. 1, lines 14-20; col. 2, lines 41-43.

Midha et al. teach pharmaceutical compositions (delayed release dosages, pulsatile release dosage forms) for treating ADD, ADHD, narcolepsy and acute depression, the compositions containing effective amounts of the active agents d-threo-methylphenidate and amphetaminil or pharmaceutically acceptable salts thereof. The compositions may also comprise two individual dosage units, wherein each unit may have a different drug release profile, for example one dosage unit may have "immediate" release and the other may have "medium" release

capabilities. Please see col. 3, lines 56-64; col. 5, lines 26-33; col. 6, lines 20-24; col. 7, lines 44-50; col. 9, lines 24-30 and lines 64-66; col. 10, lines 24-55 and lines 60-66.

Wolter et al. or Midha et al. do not disclose a composition comprising the isomer (R,R'),(R,S')-amphetaminil substantially free of (S,R),(S,S')-amphetaminil; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Wolter or Midha to contain one isomer over the other because isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233. Such a modification would have been motivated by the reasoned expectation of producing a pharmaceutical composition with optimum therapeutic effect.

With respect to the claimed dosage amount and percent weight of the claimed isomer of amphetaminil, since Wolter and Midha establish that efficacy of amphetaminil is dependent upon dose and since concentration of the active agents affects the efficacy of the pharmaceutical composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the dose and concentration of the isomer of amphetaminil such that the isomer is present at a dose and in such an amount that would enhance its effect in the patients undergoing treatment in the methods of Wolter or Midha.

Concerning the claimed used of a sulfate salt of the isomer of amphetaminil, since Midha establishes that pharmaceutically acceptable salts of an active agent are conventionally known, it

would have been obvious to one of ordinary skill in the art to further modify the composition to contain a sulfate salt of the claimed isomer of amphetaminil with the reasoned expectation that said salt form would be equally effective in treating the patients suffering from ADHD, narcolepsy or depression.

5. Claims 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al., supra in view of Wolter et al., supra.

Midha et al. teach pharmaceutical compositions for oral administration (delayed release dosages, pulsatile release dosage forms) for treating patients suffering from ADD, ADHD, narcolepsy and acute depression, the compositions containing effective amounts of the active agents d-threo-methylphenidate and amphetaminil (or salts thereof) and a pharmaceutically acceptable carrier. The compositions may also comprise two individual dosage units, wherein each unit may have a different drug release profile, for example one dosage unit may have "immediate" release and the other may have "medium" release capabilities. Please see col. 3, lines 56-64; col. 5, lines 5-11 and lines 26-33; col. 6, lines 20-24; col. 7, lines 44-50; col. 9, lines 24-30 and lines 64-66; col. 10, lines 24-55 and lines 60-66.

Midha et al. do not disclose treating Alzheimer's disease or Parkinson's disease; however, the Examiner refers to Wolter et al. which disclose a patch for transdermal administration of pharmaceutically active agents such as amphetaminil. Wolter et al. further disclose that said patches are useful in methods for treating patients suffering from Parkinson's disease or Alzheimer's disease. Please refer to the abstract; col. 1, lines 14-20; col. 2, lines 41-43.

It would have been obvious to one of ordinary skill in the art to modify the method of Midha to include the treatment of Alzheimer's disease or Parkinson's disease because one of ordinary skill in the art would reasonably expect, in view of Wolter et al.'s teaching, that amphetaminil would be equally effective in treating patients with Alzheimer's or Parkinson's disease.

Additionally, Midha et al. and Wolter et al. do not disclose administering a composition comprising the isomer (R,R'),(R,S')-amphetaminil substantially free of (S,R),(S,S')-amphetaminil; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of Midha and Wolter to contain one isomer over the other because isomers of a racemic compound are expected to have differing activities; one isomer is expected to more active than others (optically active isomer substitution was held to be obvious). See In re Anthony, 162 USPQ 594; In re Adamson, 125 USPQ 233. Such a modification would have been motivated by the reasoned expectation of effectively treating the patients suffering from the disclosed disorders.

With respect to the claimed dosage amount and percent weight of the claimed isomer of amphetaminil, since Wolter and Midha establish that efficacy of amphetaminil is dependent upon dose and since concentration of the active agents affects the efficacy of the pharmaceutical composition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the dose and concentration of the isomer of amphetaminil such that the isomer is present at a dose and in such an amount that would enhance its effect in the patients undergoing treatment in the methods of Wolter and Midha.

Concerning the claimed used of a sulfate salt of the isomer of amphetaminil, since Midha establishes that pharmaceutically acceptable salts of an active agent are conventionally known, it would have been obvious to one of ordinary skill in the art to further modify the composition to contain a sulfate salt of the claimed isomer of amphetaminil with the reasoned expectation that said salt form would be equally effective in treating the patients suffering from ADHD, narcolepsy, depression, Parkinson's disease or Alzheimer's disease.

Finally, concerning the claims drawn to parenteral administration (claim 12), mode of administration is an art-recognized result-effective variable and it would have been obvious to one of ordinary skill in the art to optimize it in the methods of Midha and Wolter.

Conclusion

Claims 1-22 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

March 21, 2002

Cybille Delacroix-Muirheid
Patent Examiner Group 1600